Characteristics of Patients Receiving Long-Term Opioid Therapy for Chronic Non-Cancer Pain: A Cross-Sectional Survey of Pain Clinic Attendees

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Abstract

Background: Characteristics of patients receiving long-term opioid therapy (>6 months) for chronic non-cancer pain are poorly understood.

Methods: We approached 260 patients presenting to a Canadian, hospital-based chronic pain clinic to complete a 20-item survey that inquired about demographic variables, pain relief, functional improvement, side-effects, and impressions regarding an educational pamphlet.

Results: 170 patients completed our survey, a response rate of 65%. Most respondents (88%; 149 of 170) were receiving long-term opioid therapy (>6 months), and of these 58% had been prescribed opioids for >5 years. The median morphine equivalent dose was 180mg/day (IQR=441). Chronic low back pain (65% of patients) was the most common complaint for which long-term opioid therapy was prescribed. The majority reported at least modest (>40%) pain relief (74%) and functional improvement (68%), and 47% reported troublesome side-effects. Most patients were receiving disability benefits (68%) and, among the 82% of respondents who were of working age (<65 years), 8% were working full-time and 11% part-time. Neither pain relief nor functional improvement were associated with employment. In an analysis adjusted for age, higher morphine equivalent dose was associated with greater self-reported pain relief (OR=1.37; 95%CI=1.00 to 1.88) and functional improvement (OR=1.14; 95%CI=1.02 to 1.27), but not opioid-related side-effects or employment.

Interpretation: Outpatients receiving care for chronic non-cancer pain at a tertiary care chronic pain clinic commonly receive high-dose, long-term opioid therapy. Most patients report at least moderate pain relief and functional improvement; side effects are common and few patients are engaged in competitive employment.

Introduction

Opioids are commonly and increasingly used for management of chronic non-cancer pain (CNCP), particularly in North America [1-3]. From 1980 to 2000 in the United States, visits for opioid prescriptions for CNCP increased from 2% to 9% of physician visits [4]. In Ontario, Canada, the number of opioid prescriptions rose from 3.7 to 4.7 million between 2005 and 2008 [5], and across the country the rate of dispensing high-dose opioid formulations (>200mg morphine equivalent [MEQ] dose/day) increased 23% from 2006 to 2011 [6]. Canada is currently the largest per-capita consumer of opioids in the world [7]. Currently, opioids are the most commonly prescribed class of medication in the United States [8] and more than 3% of adults now receive opioid therapy for more than 3 months for CNCP [9].

Despite the common use of long-term opioid therapy for CNCP, there is little known about the effectiveness of this approach and few studies capture the perspective of unselected patients. The average follow-up among randomized controlled trials of opioids for CNCP is only 5 weeks (range: 1 to 16 weeks) [10]. Furthermore, CNCP is the primary cause for years lost to disability [11]; however, many trials systematically exclude patients in receipt of disability benefits because of concerns that secondary gain will reduce the treatment effect of the study drug. There is indirect evidence for this hypothesis from a meta-analysis of 129 studies that revealed the odds of an unsatisfactory outcome in surgical patients receiving disability benefits or engaged in litigation was 3.79 times greater (95% confidence interval [CI]: 3.28 to 4.37) than similar patients not receiving disability benefits or pursuing litigation [12].

These limitations preclude confident generalizability of trial patient characteristics to real-world settings. In order to characterize patients receiving long-term opioid therapy for

CNCP we surveyed patients attending the Pain Management Centre at the Hamilton General Hospital in Ontario, Canada.

Methods

Questionnaire development

With the assistance of epidemiologists and content experts, and reference to the previous literature [13, 14], we developed a 20-item, English language questionnaire to examine characteristics of patients receiving long-term opioid therapy for chronic non-cancer pain and impressions regarding an educational pamphlet [15]. This pamphlet, titled "Are You Thinking About Taking Opioids (Painkillers) for Your Pain?" (http://nationalpaincentre.mcmaster.ca/documents/TakingOpioidsEnglishSept2012.pdf) was developed by investigators associated with the Canadian Opioid Guideline National Faculty Working Group on Knowledge Translation to Patients and the Public in an effort to provide pertinent information and encourage informed decision-making for patients considering opioid therapy for their chronic pain. This pamphlet was previously tested among a group of 20 Canadian patients with CNCP who had not been started on chronic opioid therapy [16]. Our questionnaire framed response options for attitudinal questions with a 5-point Likert scale (strongly agree, agree, undecided, disagree, strongly disagree), as a previous report has shown that closed-ended questions result in fewer incomplete questionnaires than open-ended formats [17].

We pre-tested the final questionnaire with four patients receiving opioid therapy for CNCP and asked them to comment on the clarity and comprehensiveness of the questionnaire, and the time required to complete it. No changes were recommended.

Questionnaire administration

From May 13 to August 14, 2013, an undergraduate student (HM, BM or AM) attended the Pain Management Center at the Hamilton General Hospital, Ontario, Canada, on one of 16-days during which a pain clinic was booked. The Pain Management Center is the only University affiliated pain clinic in a referral area stretching from Niagara to past Guelph, a population of over 2.5 million. It is an outpatient pain treatment centre that sees approximately 12,000 to 13,000 patient visits per year. Faculty include 7 anesthesiologists and one physiatrist.

Each patient who presented to the pain clinic was approached to complete our 20-item survey. Patients were informed that the purpose was to collect data on basic demographics, their experiences with opioid use, and their impressions of an educational pamphlet regarding opioids for CNCP. We also asked patients to report any opioids they were currently prescribed, and we confirmed this information through chart reviews by an anaesthesiologist training in chronic pain management (AZ, AM or EA). Patients were informed that they were under no obligation to complete the survey. For those who consented, the survey was administered on presentation to the clinic and collected immediately. We selected this population because we believed that they represented typical patients attending an urban tertiary care chronic pain clinic and would report high levels of long-term opioid use for CNCP, which we defined as use >6 months. Approval for our survey was granted by the McMaster Research Ethics Board.

Analysis

We generated frequencies for all collected data. Binary and categorical data were reported as proportions, and continuous data as mean and standard deviation (SD) if normally distributed and as median and interquartile range (IQR) if not. The difference between categorical variables

was assessed using Fisher's exact test and normality of continuous data was confirmed with the Shapiro-Wilk test. We calculated the morphine equivalent dose (MED) for each prescribed opioid by multiplying the quantity times the strength (i.e., milligrams per unit dispensed) times drug-specific conversion factors using an online calculator developed by the Washington State Agency Medical Directors' Group [18]. In 2007 the Washington State Agency Medical Directors' Group published the recommendation that opioid therapy among patients with CNCP should not exceed 120mg MED daily [19]. In 2010 the Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain defined 200mg MED as a "watchful" dose. [20,21]. We calculated the proportion of CNCP patients receiving long-term opioid therapy that exceeded these thresholds.

To examine the association of MED with pain relief (<40% vs. ≥40% pain relief), functional improvement (<40% vs. ≥40% improvement), employment (not employed vs. full or part-time employment) and self-reported adverse events (problematic side-effects vs. not), we carried out univariable and multivariable (adjusted for age) logistic regression analyses. Because of the skewed non-normal distribution of MED, we log transformed these data for analyses and the approximation to the normal distribution was confirmed with a Shapiro-Wilk test (p=0.43). We hypothesized, *a priori*, that higher MED would be associated with better outcomes and greater risk of adverse events, and that older age would be associated with worse outcomes and greater risk of adverse events. We calculated that we would require at least 20 completed surveys that endorsed the least common outcome category for each dependant variable in order to ensure that our regression model was reliable (10 respondents for each independent variable considered) [22]. The variance inflation factor for our

independent variables was 1, indicating no important multicollinearity [23]. We explored the association among respondents of working age (<65 years) between reporting ≥40% pain relief or ≥40% functional improvement with employment status using the Spearman correlation coefficient (ρ). All comparisons were 2-tailed and a variable was considered statistically significant if it had a p-value <0.05. We performed all analyses using PASW Statistics 18 statistical software (SPSS Inc., Quarry Bay, HK).

Results

We approached 260 patients with a primary complaint of CNCP to complete our survey; 170 gave informed consent for access to their medical records and provided a completed survey for a response rate of 65%. Of these, 9 reported no use of opioids; however, our chart review revealed that 2 were prescribed fentanyl patches. 161 respondents reported a prescription for opioids, but our chart review found that 9 were not prescribed opioids. Chart review revealed that 26 patients (18%) failed to report a confirmed prescription for opioids, 20% (30 of 149) reported receiving an opioid they were not, and 15% (23 of 149) reported use of a drug they believed was an opioid (e.g. Gabapentin) (Table 1).

Among 154 respondents with a confirmed prescription for an opioid, 149 CNCP patients (88% of respondents) were receiving long-term opioid therapy (>6 months), and of these patients 58% had been prescribed opioids for >5 years (Table 2). Respondents were only asked to complete the majority of survey questions if they were receiving long-term opioid therapy, and the 2 patients who falsely believed they were not prescribed an opioid did not complete most of the survey and were therefore excluded from most of our analyses.

Most patients prescribed long-term opioid therapy were female (61%) and the average age was 53 (SD= 13) (Table 2). Opioid dose among patients was not normally distributed (Shapiro-Wilk, $p<0.01$) and the median MED was 180mg/day (IQR=441). The majority of respondents (64.3%) exceeded the 120 mg MED/day threshold recommended by the Washington State Agency Medical Directors' Group [19], and 47% of respondents exceeded the watchful dose threshold of 200mg MED/day suggested by the Canadian opioid guideline [21].

The most common complaint for which long-term opioid therapy was prescribed was chronic low back pain (65% of patients) (Table 2). Most patients were receiving disability benefits (68%) and, among those of working age (<65 years), only 8% were working full-time and 11% part-time hours (Tables 2 & 3). Pain relief was reported more often than functional improvement; 74% reported >40% pain relief and 68% reported >40% functional improvement ($p<0.01$). Forty-seven percent endorsed problematic side-effects associated with opioid use (Table 3). In an analysis adjusted for age, higher morphine equivalent dose was associated with greater self-reported pain relief (OR=1.37; 95%CI=1.00 to 1.88) and functional improvement (OR=1.14; 95%CI=1.02 to 1.27), but not troublesome side-effects or employment (Appendix). Older age was significantly associated with reporting greater functional improvement (OR=1.44; 95%CI=1.03 to 2.00), and reduced odds of employment (OR=0.59; 95%CI=0.36 to 0.97) (Appendix). We found no association between employment and pain relief ($\rho= -0.05$, $p=0.59$) or employment and functional improvement ($\rho <0.01$, $p=0.97$).

Regarding the educational pamphlet, 75% of respondents reported that they were already aware of the information provided. Seven percent indicated they were considering stopping opioid therapy after reading the pamphlet, and 6% reported that they would have decided against long-term opioid therapy if they had read the pamphlet when approached with the option to pursue opioid therapy. Most respondents felt the pamphlet material was helpful and easy to understand (Table 4).

Discussion

High-dose, long-term opioid use is common among patients attending the Pain Management Center at the Hamilton General Hospital, and many patients exceed guideline recommendations for the maximum daily MED or watchful dose. Most patients report substantial improvements in pain and function; however, only a minority are engaged in competitive employment. A substantial minority of patients were unaware of what opioids they were prescribed, or mistook non-opioid medications for opioids. Of those patients taking long term opioids, the majority (75%) reported already being aware of important issues associated with taking opioids.

Our study has several strengths. Our response rate of 65% provides assurances that our findings are representative of CNCP patients attending the Pain Management Center at the Hamilton General Hospital. We pilot tested our survey among eligible patients prior to administration, and we independently confirmed all patient's opioid prescriptions through chart review.

One limitation of our study is its generalizability because of our focus on a single hospital-based pain clinic; however, the Hamilton General Hospital Pain Management Center has a catchment area that includes over 2.5 million individuals, which suggests that our findings are applicable to many Canadian CNCP patients referred for tertiary pain management. We measured pain relief and functional improvement from baseline in a cross-sectional survey which is subject to recall bias. Further, although we purposely chose non-clinicians to administer all surveys, some patients may have felt obligated to report improvement in pain and function to justify their long-term opioid use. Finally, we asked patients to report whether

or not they would consider stopping opioid therapy after reading an educational pamphlet, and it is likely that limited patients would endorse this decision due to cognitive dissonance.

We found both a high proportion of long-term opioid use and high doses of opioids prescribed. This may reflect the fact that many primary care physicians refuse to prescribe opioids at all and refer to a pain clinic, or that once a threshold dose (i.e. the watchful dose) is reached referral takes place and even if a patient is stable primary care physicians may be unwilling to resume analgesic management of the patient. Von Korff and colleagues studied adult members of 2 health plans serving over 1% of the US population from 1997 to 2005 [24]. They found that the majority of long-term opioid users received less than 20 mg MED per day, which is considerably less than our respondent's median of 180 mg MED per day. This may be cause for concern given evidence from observational studies that have found CNCP patients receiving high-dose opioid therapy are at greater risk for fractures, road trauma, and opioid related mortality [25-29].

We found that the majority of our respondents reported moderate improvement in both pain relief and functional ability with long-term opioid therapy; however, less than 1 in 5 patients were able to sustain even part-time work and we found no evidence of an association between self-reported improvement and gainful employment. Among our respondents, higher MED was associated with greater self-reported pain relief and functional improvement, but not employment. A subgroup analysis within a recent systematic review of strong versus weaker opioids suggested a benefit of stronger opioids over non-narcotic analgesics in pain relief but not functional restoration [10]. This positive result was based on 2 trials with important limitations [30] and the subgroup analysis failed to meet important criteria for credibility [31].

Older age was paradoxically associated with greater self-reported functional improvement and reduced odds of employment; however, the latter association has been well established in the literature [32]. There are no randomized controlled, long-term trials on the efficacy and safety of opioids for CNCP, and existing data from observational studies are inconclusive [33, 34]. As a result, it remains uncertain if the benefits of long-term opioid therapy for CNCP outweigh the risks.

Rigorously conducted randomized controlled trials are urgently needed to establish the role of long-term opioid therapy in management of CNCP. Many CNCP patients are of working age, and trials studying this population should include employment as an outcome measure. Prospective studies enrolling CNCP patients at the time they are deciding whether or not to pursue opioid therapy are required to further explore the impact of the educational pamphlet we administered. We found that many CNCP patients receiving long-term opioid therapy are unclear about what opioids they have been prescribed, and this indicates there is a role for greater education about opioids and raises the possibility that some patients are not aware of the benefits and risks of the analgesics they are taking. Formal study of efforts to improve communication and understanding in the area are warranted.

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Table 1: Patient-Reported vs. Confirmed Prescription for Opioids (n=149)

	Codeine	Oxycodone	Tramadol	Hydromorphone	Methadone	Morphine	Other Opioid
No. of Patients with a confirmed prescription	17 (12%)	51 (35%)	8 (5%)	52 (35%)	16 (11%)	16 (11%)	18 (12%) *
No. of patients that did not report a confirmed prescription	3 (2%)	0	3 (2%)	5 (3%)	1 (1%)	4 (3%)	10 (7%) *
No. of patients that reported a prescription they did not have	6 (4%)	7 (5%)	1 (1%)	10 (7%)	2 (1%)	6 (4%)	26 (18%) **

* These were fentanyl patches in all cases

** Respondents listed the following drugs as opioids: Desipramine, Nortriptyline, Gabapentin, Baclofen, Lorazepam, Nabilone, Pregabalin, Naproxen, and Duloxetine

Table 2: Characteristics of Patients Receiving Long-Term Opioid Therapy (n=145)

Age, mean (SD)	52.5 years (13.1)
Gender (n=150), n (%)	
Female	90 (62.1%)
Male	55 (37.9%)
Educational level, n (%)	
Not completed high school	26 (17.9%)
High school graduate	41 (28.3%)
College degree	55 (37.9%)
University degree	23 (15.9%)
Duration of Opioid Use, n (%)	
6 months to 1 year	12 (8.3%)
1 to 5 years	49 (33.8%)
>5 to 10 years	44 (30.3%)
>10 years	40 (27.6%)
Opioid Use, n (%)*	
Hydromorphone	52 (35.9%)
Oxycodone	51 (35.2%)
Codeine	17 (11.7%)
Fentanyl	16 (11.0%)
Methadone	16 (11.0%)
Morphone	16 (11.0%)
Tramadol	8 (5.5%)
Morphine Equivalent Dose, median (IQR)	180mg/day (441)
Presenting Clinical Condition, n (%)*	
Chronic low back pain	94 (64.8%)
Chronic neck pain	46 (31.7%)
Fibromyalgia	30 (20.7%)
Chronic headaches	26 (17.9%)
Rheumatoid arthritis	21 (14.5%)
Diabetic neuropathy	12 (8.3%)
Chronic whiplash	7 (4.8%)
Currently receiving disability (wage replacement) benefits, n (%)	
Yes	99 (68.3%)
No	46 (31.7%)

* the total is greater than 145 as patients could endorse more than 1 response option

Table 3: Patient Reported Impact of Long-Term Opioid Therapy

Degree of pain relief (n=143), n (%)	
<20%	11 (7.7%)
21% to 40%	26 (18.2%)
41% to 60%	49 (34.3%)
61% to 80%	48 (33.6%)
>81%	9 (6.3%)
Degree of functional improvement (n=142), n (%)	
<20%	14 (9.9%)
21% to 40%	32 (22.5%)
41% to 60%	50 (35.2%)
61% to 80%	38 (26.8%)
>81%	8 (5.6%)
Employment status (n=144), n (%)	
Full time hours, unmodified duties	5 (3.5%)
Full time hours, modified duties	5 (3.5%)
Part time hours, unmodified duties	6 (4.2%)
Part time hours, modified duties	8 (5.6%)
Not working	103 (71.5%)
Housekeeper/stay-at-home parent	3 (2.1%)
Student	1 (0.7%)
Retired	13 (9.0%)
The side-effects associated with opioid use are problematic (n=142), n (%)	
Strongly agree	28 (19.7%)
Agree	38 (26.8%)
Undecided	17 (12.0%)
Disagree	33 (23.2%)
Strongly disagree	26 (18.3%)

Table 4: Patient's Impressions of the Educational Pamphlet "Are You Thinking About Taking Opioids for Your Pain?"

	Strongly agree n (%)	Agree n (%)	Uncertain n (%)	Disagree n (%)	Strongly disagree n (%)
I was aware of this information before starting on long-term opioid therapy (n=143)	43 (30.1%)	64 (44.8%)	18 (12.6%)	10 (7.0%)	8 (5.6%)
This information makes me feel more positively about long-term opioid therapy (n=143)	25 (17.5%)	61 (42.7%)	43 (30.1%)	13 (9.1%)	1 (0.7%)
If I had this information before I began long-term opioid therapy, I would have decided against long-term opioid therapy (n=143)	1 (0.7%)	7 (4.9%)	23 (16.1%)	66 (46.2%)	46 (32.2%)
Having read this information now, I am thinking about stopping or decreasing my use of opioids (n=143)	0	10 (7.0%)	24 (16.8%)	53 (37.1%)	56 (39.2%)
The pamphlet was too complicated/confusing (n=142)	1 (0.7%)	4 (2.8%)	16 (11.3%)	66 (46.5%)	55 (38.7%)
The pamphlet provided too much information (n=141)	0	6 (4.3%)	16 (11.3%)	72 (51.1%)	47 (33.3%)
The pamphlet provided too little information (n=141)	3 (2.1%)	21 (14.9%)	19 (13.5%)	65 (46.1%)	33 (23.4%)
Reading the pamphlet answered all my questions about long-term opioid therapy (n=141)	22 (15.6%)	55 (39.0%)	38 (27.0%)	23 (16.3%)	4 (2.1%)
Reading the pamphlet reduced my fears about long-term opioid use (n=141)	12 (8.5%)	51 (36.2%)	48 (34.0%)	24 (17.0%)	6 (4.3%)
Reading the pamphlet increased my fears about long-term opioid use (n=141)	0	16 (11.3%)	20 (14.2%)	73 (51.8%)	32 (22.7%)

Appendix: Association of Morphine Equivalent Dose with Pain Relief, Functional Recovery, Employment status, and Adverse Events

Appendix Table 1: Association of Age and Morphine Equivalent Dose with Reporting >40% Pain Relief

Variable	**Bivariate Analysis** odds ratio (95% CI)	**p-value**	**Multivariable Analysis** odds ratio (95% CI)	**p-value**
Age by decade	1.08 (0.77 to 1.52)	0.66	1.15 (0.82 to 1.61)	0.43
logMED (per 100 units)	1.32 (0.97 to 1.79)	0.08	1.37 (1.00 to 1.88)	0.05

Appendix Table 2: Association of Age and Morphine Equivalent Dose with Reporting >40% Functional Improvement

Variable	**Bivariate Analysis** odds ratio (95% CI)	**p-value**	**Multivariable Analysis** odds ratio (95% CI)	**p-value**
Age by decade	1.33 (0.97 to 1.84)	0.08	1.44 (1.03 to 2.00)	0.03
logMED (per 100 units)	1.32 (1.00 to 1.76)	0.05	1.44 (1.07 to 1.95)	0.02

Appendix Table 3: Association of Age and Morphine Equivalent Dose with Employment (full or part-time)

Variable	**Bivariate Analysis** odds ratio (95% CI)	**p-value**	**Multivariable Analysis** odds ratio (95% CI)	**p-value**
Age by decade	0.59 (0.36 to 0.97)	0.04	0.59 (0.36 to 0.97)	0.04
logMED (per 100 units)	0.82 (0.57 to 1.17)	0.28	0.80 (0.56 to 1.15)	0.23

Appendix Table 4: Association of Age and Morphine Equivalent Dose with Reporting Troublesome Side Effects

Variable	**Bivariate Analysis** odds ratio (95% CI)	**p-value**	**Multivariable Analysis** odds ratio (95% CI)	**p-value**
Age by decade	0.88 (0.66 to 1.19)	0.42	0.87 (0.64 to 1.18)	0.36
logMED (per 100 units)	0.94 (0.73 to 1.22)	0.66	0.92 (0.70 to 1.20)	0.54

Key: 95% CI = 95% confidence interval